Summary of Informed Consent Process, Non-English Speaking

June 2024

(Previous for March 2024 in green below)

An audit was conducted of all non-English speaking participants enrolled in CCR studies March 1, 2024, through May 29, 2024. A total of 44 (58) participants were reviewed. Twenty-nine (66%) [29 (50%)] of participants had at least one issue identified at the time of the audit related to the informed consent process, including findings related to PRES embedded agreement answers. This is a 16% increase in errors compared to the previous audit. In addition, the percentage of findings that required reporting to the IRB increased from the audit performed in March – 26% versus 19%.

The following were issues of noncompliance with NIH Policy 301 that required reporting to the IRB:
(Those issues without a green number were not found in the previous audit)

- RNI was not submitted when short form process was used – 5
- Non-English-speaking participant initialed embedded questions on English long form consent – 3 (3)
- CRIS note did not indicate why verbal assent was not obtained as required per protocol for 7-year-old participant (7-12yo per protocol) – 1
- NIH Administrative section not completed at all – 3 (1)

Below is a summary table of other audit findings:

Issue Found	**Number of patients**	**Percentage of total**	**Action Required**
Embedded agreements answered incorrectly in PRES	5 (7)	11% (12%)	Correct PRES
NIH Administrative Section completed only on long OR short form during the short form process	2 (6)	5% (11%)	Minor deviation
Incorrect selection made in NIH Administrative Section	6 (4)	14% (7%)	none
CRIS Documentation of Research Consent template – not all types of consent selected	2	5%	Correct note, if possible
Informed consent documentation note contained incorrect or missing information	7 (3)	16% (5%)	Correct note, if possible
Interpreter not identified in CRIS note	1 (3)	2% (5%)	Correct note, if possible
Incorrect version of short form used	3 (3)	7% (5%)	Minor deviation

On a positive note, there were no missing Documentation of Research Consent notes for any patient reviewed. This is the first Informed Consent audit without that reportable finding.

Reminders:

- When the translated long form is given to the participant after consent was obtained using the short form process, please addend the Documentation of Research Consent note for the short form process to indicate that the translated long form was provided.
- Non-English-speaking participant **MUST NOT** sign or initial any English informed consent since they cannot read it.

Reminders, continued:

- An RNI must be submitted to the IRB within 7 days of using the short form consent process, regardless of the risk level of the study. Please include the language of short form used and the date of consent to allow for verification of RNI submission during a review process.
- Select **ALL types** of consent used in the Documentation of Research Consent template.
- If assent is required per protocol and is not obtained for any reason, the CRIS note must specify why assent was not obtained.
- Remember to complete all NIH Administrative sections when an interpreter is used:
    - Choose the appropriate option depending on if the interpreter also served as the witness.
    - If a translated long form is used, the second option is **always** selected since no witness is required.